K002523

OCT - 6 2000

August 14, 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 3-Port Console 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura D. Seneff, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name	:	Advantage™ Drive System
Common Name	:	Drive System
Classification Names	:	1. Ear, Nose and Throat Electric or Pneumatic Surgical Drill 874.4250 2. Electric Cranial Drill Motor 882.4360 3. Bone Cutting Instrument and Accessories 872.4120 4. Surgical Instrument Motors and Accessories/ Attachments 878.4820.
Proposed Class/Device	:	II
Product Code	:	HRX , ERL

D. Predicate/Legally Marketed Devices

E9000™ System
Linvatec Corporation

Universal Drive System (PowerPro™ Electric System)
Linvatec Corporation

E. Device Description

The Advantage™ Drive System console is a combination of Linvatec's E9000™ console and PowerPro™ console. The combination of the handpiece drive system and low-flow irrigation pump of the E9000™ console, with the universal power source of the PowerPro™ console, allows the user to operate all of the associated handpieces of both systems from one console.

F. Intended Use

The Advantage™ Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.

G. Substantial Equivalence

The Advantage™ Drive System is substantially equivalent in design, function and intended use to the E9000™ System (Linvatec Corporation) and the PowerPro™ Electric System (Linvatec Corporation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Ms. Laura D. Seneff, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773

Re: K002523
Trade Name: Advantage ™ Drive System
Regulatory Class: II
Product Code: HBC, GEY
Dated: August 14, 2000
Received: August 15, 2000

Dear Ms. Seneff:

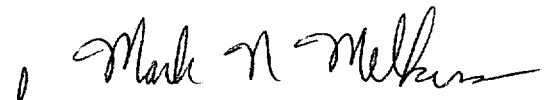
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002523

Device Name: Advantage™ Drive System

Indications for Use:

The Advantage™ Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Mark N Milkus

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002523